



Update from the European Commission's Working Group meeting on Foods for Specific Groups, 15 November 2013

The European Commission held its third technical working group meeting on Foods for Specific Groups (FSG) with Member States (MS) on 15 November 2013. This was a short meeting to build on previous discussions to tease out some of the issues that need further consideration regarding which rules on labelling, presentation, advertising, and promotional and commercial practices, which apply to Infant formula, should also apply to infant formula presented as medical foods.

Two documents summarising the issues for discussion were circulated to member states by the Commission shortly before the meeting. These covered:

- Requirements for Food for Special Medical Purposes for infants
- Pesticides in food for infants and young children

Requirements for Food for Special Medical purposes for infants

Previously, at the Expert Group meeting of 13 September 2013, a preliminary discussion was held with MS experts on the provision of Art. 11(1)(g) of the FSG Regulation which requires that specific rules are set in delegated acts for Food for Special Medical Purposes (FSMP) for infants, with respect not only to compositional requirements, but also on pesticides, labelling, presentation, advertising, and promotional and commercial practices, as appropriate.

However further discussion on the other requirements that should apply to FSMPs for infants was needed. In particular, it appeared that Member States' experts' consideration of what requirements should apply to FSMPs for infants is influenced by their experience at national level with different types of products that are marketed as FSMPs on the basis of a loose interpretation of the definition.

Discussions focused on whether stricter requirements should be set for FSMPs for infants and whether these products should comply with the requirements applicable to "normal" formula, in particular with respect to labelling and marketing. The group also considered whether certain requirements applicable to "normal" formula should be extended, but underlining that adaptation is needed in certain cases, in order to take into account the specific use of FSMPs.

It is clear that MS categorise products differently, due to differences in interpretation of what constitutes an FSMP. This has led to a wide variety of products on the market. The Commission highlighted that in future, Article 3 of FSG Regulation will provide a procedure to harmonise categorisation of foods, however, to aid current discussions, the commission has asked MS to submit lists of types of FSMPs for infants notified at national level. This will help inform discussions on which provisions should be applicable to these foods.

UPDATE INTENDED FOR INTERESTED PARTIES

Considerations on the applicability of certain articles of Directive 2006/141/EC on infant formula and follow-on formula are outlined below:

Article 13(1)(a) of Directive 2006/141/EC – statement on suitability of infant formula for infants from birth when they are not breast fed

Some MS consider that there is already a requirement under Article 4 of Directive 1999/21/EC to describe the intended use of the product (“Dietary management of...”) and the intended age group, therefore repeating Article 13(1)(a) of Directive 2006/141/EC is not necessary.

Article 13(3) – prohibition of the words ‘humanised’, ‘maternalised’ ‘adapted’ or similar terms.

It was considered whether the principles behind Article 13(3) should apply to FSMP of infants, and whether the use of the term ‘adapted’ should be permitted in the context of describing how the formula is adapted to meet the nutritional needs of the specific condition/disease.

Article 13(4)(a) of Directive 2006/141/EC – statement concerning the *superiority of breastfeeding*

Member States discussed examples of FSMP for infants (for use from birth), where, exclusive breastfeeding is either not adequate or breastfeeding is specifically contraindicated because of the condition/disease, such as Maple Syrup Disease. In such cases, it was considered that the statement under Article 13(1)(a) is not suitable or should be adapted.

Article 13(6) – nutrition and health claims

Several Member States' experts flagged that a reflection on the use of claims for FSMPs for infants should be carried out. The Commission also raised the question whether there should be a distinction between before and after 6 months of age and whether there is a need for claims on these foods.

Article 14(1) – Restrictions on advertising

During the Expert Group meeting of 13 September, member states agreed that the restrictions on advertising and promotion should also apply to FSMP for infants. However, concerns have been raised, in particular that extending this provision to FSMPs for infants would make it difficult for operators to communicate with caregivers / Health Care Professionals and would deprive them of useful information about the use of the product. Issues would, reportedly arise because communication on FSMPs often mentions the brand name and is done in a number of ways (not only in scientific publications). Further consideration is needed as to what information is essential to ensure safe use of the product and whether samples to healthcare professionals, but not parents/carers.

Pesticides in food for infants and young children

During the previous discussion's on 15 September, it appeared that MS agree that rules on pesticides that are applicable to infant formulae (IF) and follow-on formulae (FoF) should also apply to FSMPs for infants.

UPDATE INTENDED FOR INTERESTED PARTIES

In relation to the document circulated on pesticides, there was little discussion, but in light of the need to review the current provisions, there was general agreement to ask the European Food Safety Authority (EFSA) to review the scientific opinions from 1997/1998 on setting specific requirements on the use of pesticides in products intended for the production of and on pesticide residues in infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children.

Next meeting

Next meeting will be in the New Year – date to be confirmed.

Comments

We would welcome any further comments on any of the issues raised above or any other aspects of the FSG Regulation. **Please e-mail your comments to Parnutnotification@dh.gsi.gov.uk by 11 January 2014.**

Prepared by Nutrition Legislation Team, Obesity & Food Policy Branch, Health & Wellbeing Division